Stago

K111822

OCT 26 2011

510(k) Summary

Submitter's Information

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Date Prepared: October 25, 2011

Application Correspondent and Contact Person:

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Device Names :

Trade names (products sold separately)	Common names	Classification name	Product Code
STA® - Liquid Anti-Xa	Heparin Assay	Heparin Assay 21 CFR 864.7525	KFF
STA® - Multi Hep Calibrator	Heparin Calibrator	Calibrator, secondary 21 CFR 862.1150	JIT
STA® - Quality HNF/UFH	Heparin Control	Plasma, coagulation control 21 CFR 864.5425	GGN
STA® - Quality HBPM/LMWH	Heparin Control	Plasma, coagulation control 21 CFR 864.5425	GGN

Predicate Devices

Predicate Device name	510(k) number
STA® - Rotachrom® Heparin	K010455
STA® - Calibrator HBPM/LMWH	K010350
STA® - Hepanorm® H {formerly cleared as Hepanorm® Calibration Plasma Set}	K854762
STA® - Heparin Control	K943520
STA® - Quality HBPM/LMWH	K010324

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Device Intended Use

- ✓ **STA® - Liquid Anti-Xa**: The STA® - Liquid Anti-Xa kits are intended for use with STA-R®, STA Compact® and STA Satellite® analyzers, for the quantitative determination of the plasma levels of unfractionated (UFH) and low molecular weight (LMWH) heparins by measuring their anti-Xa activity on antithrombin in a competitive assay using a synthetic chromogenic substrate.

- ✓ **STA® - Multi Hep Calibrator**: The STA® - Multi Hep Calibrator is a set of calibrator plasmas intended for use with STA-R®, STA Compact®, and STA Satellite® analyzers, for the calibration of heparin (UFH and LMWH) activity assay by measuring the anti-Xa activity.

- ✓ **STA® - Quality HNF/UFH:** The STA® - Quality HNF/UFH kit is a set of two plasmas intended for the quality control of unfractionated heparin (UFH) activity assay by measuring the anti-Xa activity performed on STA-R®, STA Compact®, and STA Satellite® analyzers.

- ✓ **STA® - Quality HBPM/LMWH**: The STA® - Quality HBPM/LMWH kit is a set of two plasmas intended for the quality control of low molecular weight heparin (LMWH) activity assay by measuring the anti-Xa activity performed on STA-R®, STA Compact®, and STA Satellite®.

Device descriptions

- ✓ **STA® - Liquid Anti-Xa**:

  The STA® - Liquid Anti-Xa is a chromogenic assay technique used for determination of the level of UFH and LMWH that have high affinity for antithrombin by measuring their anti-Xa activity.

  The normal function of a molecule of factor Xa, when present in plasma, is to cleave its natural substrate, prothrombin, to generate thrombin, the enzyme responsible for the formation of the fibrin clot. In the presence of heparin, competition occurs between this mechanism and the inhibitory mechanism exerted by the heparin-antithrombin complex, this inhibition being largely responsible for the anticoagulant action of heparin.

  The proposed method is a one-step reaction based on a similar principle: as soon as factor Xa is added to the plasma-substrate mixture, two reactions take place simultaneously, namely,

  – hydrolysis of the substrate by factor Xa

  – inhibition of factor Xa by the heparin-antithrombin complex*.

  After the necessary period of time for the competitive reaction to reach equilibrium, the quantity of paranitroaniline that is released is inversely proportional to the concentration of heparin present in the test medium.

  * The heparin-antithrombin complex is made up from the heparin and the antithrombin (AT) peculiar to the patient.

- ✓ **STA® - Multi Hep Calibrator**
  The STA® - Multi Hep Calibrator reagents are lyophilized human plasmas at five different heparin concentrations. They are used to create the calibration curve on STA-R®, STA Compact®, and STA Satellite® analyzers performing the chromogenic method for heparin (UFH and LMWH) using STA® - Liquid Anti-Xa.
  Three kinds of calibration are possible, depending on the type of molecule to be determined:
  – a calibration with the Reagents 1, 2, 3, 4 and 5 for UFH and/or LMWH assays,
  – a calibration with the Reagents 1, 2 and 4 dedicated to UFH assays,
  – a calibration with the Reagents 1, 3 and 5 dedicated to LMWH assays.

- ✓ **STA® - Quality HNF/UFH**
  The STA® - Quality HNF/UFH reagents are lyophilized human plasmas at two different UFH concentrations. They are used for the quality control of UFH activity assay by measuring the anti-Xa activity using the chromogenic method STA® - Liquid Anti-Xa performed on STA-R®, STA Compact®, and STA Satellite® analyzers.

- ✓ **STA® - Quality HBPM/LMWH**
  The STA® - Quality HBPM/LMWH reagents are lyophilized human plasmas at two different LMWH concentrations. They are used for the quality control of LMWH activity assay by measuring the anti-Xa activity using the chromogenic methods, STA® - Liquid Anti-Xa and STA® - Rotachrom® Heparin, performed on STA-R®, STA Compact®, and STA Satellite® analyzers.

Statement of technological characteristics of the device compared to predicate devices

- ✓ STA® - Liquid Anti-Xa is substantially equivalent to the predicate device, STA® - Rotachrom® Heparin (K010455) in indication/intended use, test principle, technology and performance thus yielding no new questions in safety and effectiveness.

- ✓ STA® - Multi Hep Calibrator is substantially equivalent to the predicate devices, STA® - Calibrator HBPM/LMWH Kit (K010350) and STA® - Hepanorm® H (K854762) in indication/intended use, technology and performance, thus yielding no new questions in safety and effectiveness.
  The primary difference between the subject product and predicate devices is that the new calibrator kit is intended for use with both Unfractionated and Low Molecular Weight Heparin testing.

- ✓ STA® - Quality HNF/UFH is substantially equivalent to the predicate device STA® - Heparin Control (K943520) in indication/intended use, technology and performance, thus yielding no new questions in safety and effectiveness.

- ✓ STA® - Quality HBPM/LMWH is substantially equivalent to the predicate device STA® - Quality HBPM/LMWH (K010324) in indication/intended use, technology and performance, thus yielding no new questions in safety and effectiveness. The new STA® - Quality HBPM/LMWH is a modification to the current kit STA® - Quality HBPM/LMWH, the primary difference is that the new STA® - Quality HBPM/LMWH is intended for use with LMWH testing performed by STA® - Liquid Anti-Xa in addition to the current assay STA® - Rotachrom® Heparin (K010455).

Summary Performance Characteristics

- ✓ *Precision*

  Precision studies were performed according to the CLSI guideline EP5-A2 using samples containing heparin (22 days, 2 runs per day). The following results have been obtained:

Hybrid calibration (5-point calibration)			Sample 1 (UFH)	Sample 2 (UFH)	Sample 3 (UFH)	Sample 4 (LMWH)	Sample 5 (LMWH)	Sample 6 (LMWH)
Mean	$\bar{X}$	IU/mL	0.21	0.55	0.97	0.86	1.48	1.75
Repeatability	SD	IU/mL	0.013	0.017	0.033	0.027	0.045	0.050
	CV	%	6.2	3.1	3.4	3.1	3.0	2.9
Within-laboratory precision	SD	IU/mL	0.021	0.036	0.053	0.041	0.075	0.087
	CV	%	9.9	6.6	5.5	4.8	5.1	5.0

Dedicated calibration (3-point calibration)			Sample 1 (UFH)	Sample 2 (UFH)	Sample 3 (UFH)	Sample 4 (LMWH)	Sample 5 (LMWH)	Sample 6 (LMWH)
Mean	$\bar{X}$	IU/mL	0.22	0.55	0.97	0.86	1.48	1.75
Repeatability	SD	IU/mL	0.012	0.017	0.034	0.028	0.045	0.050
	CV	%	5.6	3.0	3.5	3.2	3.1	2.8
Within-laboratory precision	SD	IU/mL	0.020	0.033	0.050	0.045	0.078	0.089
	CV	%	9.2	6.1	5.1	5.2	5.3	5.1

- ✓ *Detection Limit - Working Range*

  The limit of detection and linearity were assessed for each method according to the CLSI guidelines EP17-A and EP6-A respectively.

  In the UFH/LMWH method with the STA® - Multi Hep Calibrator (5-point calibration) the detection threshold on the STA-R® is 0.10 IU/ml (UFH and LMWH) and the linearity range extends to 1.10 IU/ml for the UFH and to 2.00 anti-Xa IU/ml for the LMWH.

  In the UFH method with the STA® - Multi Hep Calibrator (UFH 3-point calibration), the detection threshold on the STA-R® is 0.10 IU/ml and the linearity range extends to 1.10 IU/ml.

In the LMWH method with the STA® - Multi Hep Calibrator (LMWH,3-point calibration) the detection threshold on the STA-R® is 0.10 anti-Xa IU/ml and the linearity range extends to 2.00 anti-Xa IU/ml.

✓ *Interfering substances*

The STA® - Liquid Anti-Xa method (UFH and LMWH protocols) is insensitive to the following substances: hemoglobin (up to 1.5 g/l), conjugated bilirubin (up to 288 mg/l - 342 µmol/l), unconjugated bilirubin (up to 138 mg/l - 236 µmol/l) and triglycerides (up to 6.9 g/l - 8 mmol/l). The tests were performed according to the CLSI guideline EP7-A2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Diagnostica Stago, S.A.S.
c/o Mr. Carlo d'Alessandro
Director, IVD Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania, 10
Rome, Italy 00153

OCT 26 2011

Re: k111822
Trade/Device Name: STA®- Liquid Anti-Xa
STA®-Multi Hep Calibrator
STA®-Quality HNF/UFH
STA®-HBPM/LMWH
Regulation Number: 21 CFR § 864.7525
Regulation Name: Heparin Assay
Regulatory Class: Class II
Product Code: KFF; JIS; GGN
Dated: September 22, 2011
Received: September 26, 2011

Dear Mr. d'Alessandro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Stago

1.3 Indications for Use Statements

510(k) Number (if known): K111822

Device Name: STA® - Liquid Anti-Xa

Indications for Use:

The STA® - Liquid Anti-Xa kits are intended for use with STA-R®, STA Compact® and STA Satellite® analyzers, for the quantitative determination of the plasma levels of unfractionated (UFH) and low molecular weight (LMWH) heparins by measuring their anti-Xa activity on antithrombin in a competitive assay using a synthetic chromogenic substrate.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111822

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510(k) Number (if known): k111822

Device Name: STA® - Multi Hep Calibrator

Indications for Use:

The STA® - Multi Hep Calibrator is a set of calibrator plasmas intended for use with STA-R®, STA Compact® and STA Satellite® analyzers, for the calibration of heparin (UFH and LMWH) activity assay by measuring the anti-Xa activity.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111822

Stago

510(k) Number (if known): k111822

Device Name: STA® - Quality HNF/UFH

Indications for Use:

The STA® - Quality HNF/UFH kit is a set of two plasmas intended for the quality control of unfractionated heparin (UFH) activity assay by measuring the anti-Xa activity performed on STA-R®, STA Compact® and STA Satellite® analyzers.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111822

Stago

510(k) Number (if known): k111822

Device Name: STA® - Quality HBPM/LMWH

Indications for Use:

The STA® - Quality HBPM/LMWH kit is a set of two plasmas intended for the quality control of low molecular weight heparin (LMWH) activity assay by measuring the anti-Xa activity performed on STA-R®, STA Compact® and STA Satellite® analyzers.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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